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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/555,555 | 09/25/2000 | Veronique M. Braud | SHP-PT059 | 9366 |

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EXAMINER

DECLOUX, AMY M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 01/13/2003

1K

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/555,555 | BRAUD ET AL. |
| Examiner | Art Unit | |
| Amy M. DeCloux | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 4-11-02 & 8-6-02 .

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) 1-19 and 24-29 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 20-23 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .

4) Interview Summary (PTO-413) Paper No(s). _____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: See Continuation Sheet .

Continuation of Attachment(s) 6). Other: Notice to Compy with Requirements for Sequence Disclosures.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group V (claims 20-23) in Paper No. 10, filed 4-11-02 is acknowledged. The traversal is on the ground(s) that all of the claims relate to the binding between nk cells and HLA-E. This is not found persuasive because claim 18 which is drawn to a cell which expresses HLA-E at the cell surface, does not recite anything about the binding between nk cells and HLA-E.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-19 and 24-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10, filed 4-11-02.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A) The abstract of the disclosure is objected to because there are two periods in the last sentence of the Abstract. Also, in the first line of the abstract it is not clear what is meant by the phrase "causing interaction of CD94/NKG2+ cells". Correction is required. See MPEP § 608.01(b).

B) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Sequences without SEQ ID NO: tags are disclosed in the specification, specifically pages 14, 20 and 21. Applicant is required to identify each of said sequences with a SEQ ID NO: tag. **ONLY IF SAID SEQUENCES ARE NOT IN THE PAPER COPY AND THE CRF COPY OF THE SEQUENCE LISTINGS**, Applicants are also required to resubmit a substitute disk and paper copy of the sequences according to the attached "Notice to Comply with the Sequence Rules." Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 C.F.R. 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

Information Disclosure Statement

The IDS filed 9-26-00 (Paper No. 7, has been considered, see attached, signed copy of the corresponding 1449 form. It is noted that Items AA, AB and AC have been considered only to the extent of their respective Abstract.

Additionally, unfortunately, the references and 1449 form filed 9-6-00 (Paper No. 4) are not present in the case. Applicant is kindly requested to send another copy of said 1449 form and its associated references.

Drawings

New formal drawings are required in this application because of the reasons outlined in the attached Form 948. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

C. Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 21-22, the recitation of the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for testing a compound for biological activity comprising the nk receptors CD94/NKG2A or CD94NKG2C, does not reasonably provide enablement for said method comprising any nk receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant claims are directed to a method for testing a compound for biological activity comprising contacting cells expressing CD94NKG2 receptors at the cell surface with HLA-E in the presence of the test compound, and determining whether the presence of the compound effect the binding of HLA-E to the cells. The instant specification teaches that HLA-E interacts with cells expressing CD94/NKG2A, CD94/NKG2B or CD94NKG2C, see Figure 3, but does not teach that any other CD94NKG2 receptors bind HLA-E. Nor does the art at the time the invention was made teach that any CD94NKG2 receptors (such as CD94/NKG2D CD94/NKG2E, or CD94/NKG2F) bind HLA-E (see Table 1, Posch et al (J. Biomed Scie (1998) 5:321-331 (IDS)). Therefore, it would require undue experimentation for one of skill to practice the claimed invention with any CD94NKG2 receptor other than CD94/NKG2A, CD94/NKG2B or CD94NKG2C, without further guidance from the specification.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Aldrich et al (1994) Cell 79:649-658, as evidenced by Brooks et al. Journal of Immunology (1999) 162:305-313.

Aldrich et al teach a compound consisting of the peptide consisting of the amino acid sequence AMAPRTLLL, which effects the binding of HLA-E to CD94/NKG2 receptors, as evidenced by Brooks et al. Brooks et al teach that the compound AMAPRTLLL associated with HLA-E is recognized by CD94/NKG2A. Therefore, the referenced teachings anticipate the claimed invention.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner, Group 1640
January 12, 2003
Amy M. DeCloux
1-12-03